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PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to describe the process of notifying NACHO members and distributing new NACHO research protocols for submission at member institutions.

POLICY

All new NACHO research protocols that have been reviewed and approved by the NACHO Clinical Studies Committee, have completed the regulatory process, and have been approved by the Protocol Study Chairs' IRB of record, will be distributed by the NACHO Operations Center (NACHO OC) for accrual by NACHO member sites.

PROCEDURES

I. Preparation for Notification of a New Research Protocol

1. The Protocol Study Chair will ensure that all required regulatory reviews have been completed.
2. All member institutions wishing to enroll participants on the research protocol will execute a Clinical Study Protocol Rider. (see SOP "Membership Categories, Criteria and Standards") (This needs to be completed prior to receiving protocol documents)
3. The Protocol Study Chair will send a copy of the IRB approved protocol along with all approved supporting documents to the NACHO Operations Center Study Manager (SM)
4. A protocol specific webpage will be created on the NACHO website.
5. Once all documents have been reviewed and verified, the NACHO SM will upload the approved protocol documents to the protocol webpage.
6. The NACHO SM will send a NACHO Protocol Activation notice to current NACHO members who will participate in the study.

II. Site (Institution) Activation Memo

1. Upon receipt of the fully executed Clinical Study Protocol Rider, and
2. all required documents are received by the NACHO SM from a site, and
3. a Site Initiation Visit and Database Training have occurred,
4. A dated Site Activation memo will be sent to the Site PI and appropriate personnel to be stored in the site study binder.
5. The site may then begin enrollment on the new NACHO research protocol.

MAINTENANCE RESPONSIBILITY

The NACHO SOP Ad Hoc Committee is responsible for the review of this SOP. Suggested changes must be proposed to and approved by the NACHO Executive Committee.

AUTHORIZATION

This SOP was developed by the SOP Ad Hoc Committee and reviewed and approved by the NACHO Executive Committee.

VERSION/REVISION HISTORY

Approval Date	Version	Version/Revision Summary
12/11/2017	V 1.0	Original documentation/publication.
5/25/2022	V 2.0	Updated role of NACHO Operations and Study Manager